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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/462,416	04/13/00	REVEL M	REVEL=15

001444
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HM12/1003

EXAMINER	
BASI, N	
ART UNIT	**PAPER NUMBER**
1646	10

DATE MAILED: 10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/462,416	Applicant(s) Rehovot et al
	Examiner Nirmal S. Basi	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 24, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-37* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Amendments filed 4/13/00 (paper number 5), 4/26/00 (paper number 7) and 4/24/01 (paper number 9) have been entered.

Election/Restrictions

2 Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 1-15, 32-36, drawn to chimeric construct of glycosylated soluble interleukin-6 receptor and interleukin 6 protein and biologically active analogs.

Group II. Claims 16-26, drawn to DNA encoding chimeric construct of glycosylated soluble interleukin-6 receptor and interleukin 6 protein and biologically active analogs, vector containing said construct, cell containing said vector and methods of producing said chimeric construct.

Group III. Claims 28 and 29 drawn to use of the chimeric construct of claim 1 for eliciting engraftation of human hematopoietic cells in bone marrow

transplantation. The "use" claim is interpreted by examiner as a method of treatment claim.

Group IV. Claim 30 drawn to use of the chimeric construct of claim 1 as an active ingredient for protecting liver against hepatotoxic agent. The "use" claim is interpreted by examiner as a method of treatment claim.

Group V. Claim 31 drawn to use of the chimeric construct of claim 1 as an active ingredient for increasing hematopoiesis, for treating liver or neurological conditions. The "use" claim is interpreted by examiner as a method of treatment claim.

Group VI. Claim 37 drawn to use of the chimeric construct of claim 33 for treating cancers, enhancing bone marrow transplantations, treating liver or neurological disorders, increasing hematopoiesis.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The only technical feature common to present claims is that they are concerned with sIL-6R/IL-fusion proteins. This kind of protein was however known from the prior art as disclosed in IDS references AA, AB, AC, AD, AE, AF, AG, AH, AI, and can consequently not provide a common inventive concept for the present claims. Also see the Examiners, comments disclosed in the International Preliminary Examination Report, provided by Applicant, for Application number PCT/IL98/00321. Because the special technical feature of

Group I has been found in the prior art, a technical relationship does not exist between the claimed groups. Therefore, unity of invention is lacking. Groups do not share a special technical feature in any paring because the products are structurally and functionally different and capable of separate use and manufacture.. The methods of Groups III-VI do not share a special technical feature because the methods have materially different process steps using different products and each defines a separate invention over the art. The methods of Groups II-VI do not require the products of Group I. Since no technical feature in any group, other than the main invention, is shared by any other invention, unity of invention is lacking.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claim 31 drawn to the species increasing hematopoiesis, treating liver condition and treating neurological condition.

Claim 37 drawn to drawn to the species treating cancers, enhancing bone marrow transplantations, treating liver or treating neurological disorders, increasing hematopoiesis.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument

that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the species is related to a different disease.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
September 30, 2001

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600